

Docket No.: 1516-0126PUS1
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Masaru YAMAKOSHI et al.

Application No.: 10/509,120

Confirmation No.: 3292

Filed: November 29, 2004

Art Unit: 1657

For: METHOD OF DETECTING MILD IMPAIRED
GLUCOSE TOLERANCE OR INSULIN
SECRETORY DEFECT

Examiner: P. C. Martin

DECLARATION REGARDING TRANSLATION

I, Dr. Nobuhiro Takahashi, hereby declare as follows:

1. I am a citizen of Japan, receiving mail at Moegi Patent Office, Toranomon Nakata Building 4F, 7-7 Toranomon 2-chome, Minato-ku, Tokyo 105-0001, Japan.
2. I am fluent in both the Japanese and English languages, including understanding of technical language in the field of analytic biochemistry.
3. I have reviewed both the International Application PCT/JP2003/03771, published in Japanese as WO 2003/083133 and the corresponding U.S. National Stage application no. 10/509,120.
4. The passage in U.S. National Stage application no. 10/509,120 originally translated as:

The term "characteristic value" refers to a value determined on the basis of an average of myo-inositol levels in urine samples of healthy subjects selected from those of NGT; standard deviation; and ROC (response operating characteristic) curve. When urine samples are used, the increment in urinary myo-inositol excretion between before the glucose load and at a predetermined time after the glucose load is in the range of 0 to 20 µg/mg creatinine; or 5 to 15 µg/mg creatinine; or more preferably 8 to 12 µg/mg creatinine. In addition, the characteristic value may be

changed if a large-scale examination is conducted in the future and the determination is conducted for healthy individuals selected clinically. Furthermore, the characteristic value may also vary depending on the selected populations of race, sex, and age.

was not correctly translated. A true and faithful translation is instead:

The term "characteristic value" refers to a value determined on the basis of an average of myo-inositol levels in urine samples of healthy subjects selected from those of NGT; standard deviation; and ROC (response operating characteristic) curve. When urine samples are used, the term "characteristic value" refers to a value determined on the basis of the increment in urinary myo-inositol excretion between before the glucose load and at a predetermined time after the glucose load, and is in the range of 0 to 20 µg/mg creatinine; or 5 to 15 µg/mg creatinine; or more preferably 8 to 12 µg/mg creatinine. In addition, the characteristic value may be changed if a large-scale examination is conducted in the future and the determination is conducted for healthy individuals selected clinically. Furthermore, the characteristic value may also vary depending on the selected populations of race, sex, and age.

5. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Date: April 4, 2008

By Nobuhiro Takahashi

Dr. Nobuhiro Takahashi